




UNITED STATES PATENT AND TRADEMARK OFFICE


UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,622	12/12/2001	Paul F. Laeseke	960296.98636	5043
27114	7590	05/17/2005	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8r

Office Action Summary	Application No. 10/021,622	Applicant(s) LAESEKE ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed December 17, 2004. The Examiner acknowledges the amendments to claims 5 and 10. Claims 5-8 and 10 are currently pending. Claims 1-4, 9 and 11-20 stand withdrawn from consideration without prejudice.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al. ('242). Roberts et al. teaches a biopsy sampler with a means for cauterizing the biopsy site after the biopsy is taken (see Figures 4a-4c). The sampler includes an introducer shaft (50) that is a hollow tube that is sized for insertion into the patient along an insertion path to locate a first end of the tube at a biopsy site. The first end of the shaft includes an electrically conductive surface (22) on a conductive stylet having a first end supported by the shaft that is adapted to be exposed to tissue and communicates by means of an insulated conductor (28, see column 4, lines 46-48) with a radio frequency cauterizing electrical source (see column 4, lines 40-41). A large area electrode is adapted to contact the patient without production of cauterization temperatures to complete a circuit when a monopolar electrode is used (see column 6, lines 38-46). A biopsy

Art Unit: 3736

needle (14, see column 6, lines 51-52) including a sampling means (30) is fit in the introducer shaft to be guided thereby.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ('242) in view of Lennox ('137).

Roberts et al. teaches a biopsy sampler with a means for cauterizing the biopsy site after the biopsy is taken. The sampler includes an introducer shaft (12) that is a hollow tube that is sized for insertion into the patient along an insertion path to locate a first end of the tube at a biopsy site. The first end of the tube includes an electrically conductive surface (22) that is adapted to be exposed to tissue that communicates by means of an insulated conductor (28, see column 4, lines 46-48) with a radio frequency cauterizing electrical source (see column 4, lines 40-41). A large area electrode is adapted to contact the patient without production of cauterization temperatures to complete a circuit when a monopolar electrode is used (see column 6, lines 38-46). A biopsy needle (14, see column 6, lines 51-52) including a sampling means (30) is fit in the introducer shaft to be guided thereby. After a biopsy sample is taken using the biopsy needle, the electrically conductive surface is activated to cauterize the biopsy site. The electrically conductive surface may be disposed on a stylet interfitted within the shaft (see Figure

Art Unit: 3736

8b). Roberts et al. teach all of the limitations of the claims except that the conductive surface is formed by a conductive stylet with a rounded tip and that a temperature sensor is disposed on the electrically conductive surface.

Lennox teaches a medical device for temperature controlled RF coagulation and cauterization of tissue. The device includes a conductive stylet (figs. 1-6 and 9) having an insulated section (39) and an exposed, distal electrically conductive surface (28,35). A large area electrode (8) is adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the cauterizing and coagulating electrical source with the electrically conductive surface through the patient. A temperature sensor (29,36) is disposed at the electrically conductive surface (28,35) in order to provide an indirect means of measuring and controlling the temperature of the tissue surrounding the electrode, so as to prevent excessive tissue damage.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to withdraw a biopsy needle from an introducer shaft similar to that of Roberts et al. after a biopsy sample is taken and to then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage and leakage, while providing an indirect means of measuring and controlling the temperature of the tissue surrounding the electrically conductive surface, so as to prevent excessive tissue damage.

Response to Arguments

6. Applicant's arguments with respect to claims 5-8 and 10 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Moorman teaches biopsy track ablation provided by microwave energy, and teaches away from the use of RF ablation as required by the amended claims. Applicant further contends that Lennox teaches that it is important to use RF power rather than microwave power, and therefore teaches away from the combination of references. These arguments are moot in view of the new grounds of rejection set forth hereinabove citing Roberts et al. ('242) and Lennox ('137).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Farhadi ('530) teaches an automated hot biopsy needle including a monopolar electrocautery source for cauterizing a biopsy track.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3736

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
May 10, 2005